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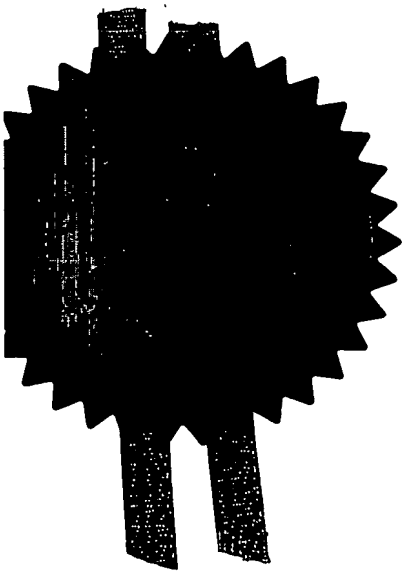

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# Request for grant of a patent

**1/77**

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| | | |
|---|---|---|
| 1. | Your reference | IMG/44825GB1 |
| 2. | Patent application number | 0324358.1 — 17 OCT 2003 |
| 3. | Full name, address and post code of the or each applicant | Vectura Ltd<br>1 Prospect West<br>Chippenham<br>Wiltshire SN14 6FH |
| | Patents ADP number | 8610727001 |
| | If the applicant is a corporate body, give the country/state of its incorporation | United Kingdom |
| 4. | Title of the invention | Inhaler |
| 5. | Name of your agent | VENNER, SHIPLEY & CO |
| | "Address for service" in the United Kingdom to which all correspondence should be sent | 20 LITTLE BRITAIN<br>LONDON<br>EC1A 7DH |
| | Patents ADP | 1669004 |

| 6. | If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or each of these earlier applications and the or each application number | Country | Priority application number | Date of filing |
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| | Priority documents | |
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| | Statement of inventorship and right to grant of a patent *(Patents Form 7/77)* | |
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| | Request for substantive examination *(Patents Form 10/77)* | |
| | Any other documents | |
| 11. | I/We request the grant of a patent on the basis of this application. | |
| | Signature: Venner, Shipley + Co. | Date: 17 October 2003 |
| 12. | Name and daytime telephone number of person to contact in the United Kingdom | Ian Grey<br>020 7600 4212 |

# Inhaler

## Description

The present invention relates to an inhalation device for oral or nasal delivery of medicament in powdered form. The invention also relates to an inhaler containing a strip of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user of the device according to the invention and, to a method of using such a device.

Oral or nasal delivery of a medicament using an inhalation device is a particularly attractive method of drug administration as these devices are relatively easy for a patient to use discreetly and in public. As well as delivering medicament to treat local diseases of the airway and other respiratory problems, they have more recently also be used to deliver drugs to the bloodstream via the lungs thereby avoiding the need for hypodermic injections.

In one type of conventional metered dose inhalation device, the powdered medicament is held in a reservoir within a dispensing device that is operable to measure out and dispense a predetermined amount of powder for each dose. However, these devices suffer from poor dose metering capability especially when the size of the dose is relatively small as it is difficult to accurately measure out small amounts of dry powder in such a device. It is also difficult to protect the drug from the ingress of moisture and to seal it from the atmosphere until it is required for administration to a patient.

It is common for dry powder formulations to be pre-packaged in individual doses, usually in the form of capsules or blisters which each contain a single dose of the powder which has been accurately and consistently measured. A blister is generally cold formed from a ductile foil laminate or a plastics material and includes a puncturable lid which is permanently heat-sealed around the periphery of the blister during manufacture and after introduction of the dose into the blister. A foil blister is preferred over capsules as each dose is protected from the ingress of water and

penetration of gases such as oxygen in addition to being shielded from light and UV radiation all of which can have a detrimental effect on the delivery characteristics of the inhaler if a dose becomes exposed to them. Therefore, a blister offers excellent environmental protection to each individual drug dose.

Inhalation devices which receive a blister pack comprising a number of blisters each of which contain a pre-metered and individually packaged dose of the drug to be delivered are known. Actuation of the device causes a mechanism to open a blister so that when the patient inhales, air is drawn through the blister entraining the dose therein which is then carried out of the blister through the device and via the patient's airway down into the lungs.

It is advantageous for the inhaler to be capable of holding a number of doses to enable it to be used repeatedly over a period of time without the requirement to open and/or insert a blister into the device each time it is used. Therefore, many conventional devices include means for storing a number of blisters each containing an individual dose of medicament. When a dose is to be inhaled, an indexing mechanism moves a previously emptied blister away from the opening mechanism so that a fresh one is moved into a position ready to be opened for inhalation of its contents.

A problem with conventional inhalation devices is that they are relatively large, heavy and difficult to operate. Despite their large size, many of them only have sufficient capacity to hold a relatively small number of doses before the device must be opened and a fresh set of blisters mounted therein. Although it may be possible to increase the number of blisters by making them smaller, this can only be achieved at the expense of reducing the dose payload or capacity of each blister. This is particularly disadvantageous when the device is to be used to deliver for example newer, less potent drugs where each blister must be able to hold a payload of somewhere in the region of 10-20mg of the drug.

Due to their nature and method of operation, conventional inhalation devices have a relatively complicated construction and consist of many separate components

making them difficult and time consuming to assemble as well as being expensive to manufacture and purchase.

A conventional inhalation device of the type described above is known from US 4,811, 731. This device is configured to receive a disc-shaped dose storage blister pack in which the doses are arranged in a generally circular pattern. A plunger is provided which moves in response to the actuation of a lever to puncture a blister disposed beneath it to enable the dose to be inhaled from the punctured blister. The device also includes a separate indexing device operable to rotate the disc so as to move a fresh blister to a puncturable position. A significant problem with this device is that the number of doses is severely limited. As can be seen from the device shown in the Figures, it is capable of receiving only eight doses at a time so frequent replacement of the disc is necessary. Although it will be appreciated that the disc can be made larger to accommodate a larger number of blisters, this would result in a significant increase in the overall size of the device making it very bulky. It is also notable that the piercing and indexing steps are controlled entirely independently of each other making the device significantly harder to use and increasing the number of components forming the device.

Another known inhalation device is described in US 6,032,666. Although this device receives a strip of blisters, it has a very complicated construction with numerous components making it hard to assemble and operate. It is limited by the fact that access to the dose contained in each blister is obtained by peeling the lid off it rather than by piercing it. Therefore, the device has a complicated mechanism for peeling the lid from the blister including a take-up spool for the peeled lid strip and a complex clutch arrangement to ensure that the same length of lid is peeled from the strip each time the device is used as more and more of the lid strip is wound around the take-up spool. These components, together with the requirement to store the peeled lid within the device, increases its complexity and overall size as well as making it harder to re-fill with a fresh strip of blisters. It will also be appreciated that this device can only be used with a strip of blisters in which the lid is peelably attached to the blister. Not only does this require a suitable adhesive, it also reduces the barrier to moisture and other environmental contaminants.

The present invention seeks to provide an inhalation device that overcomes or substantially alleviates the problems with conventional inhalation devices of the type discussed above. In particular, the invention seeks to provide a device having a significantly simpler construction than known devices that is capable of storing a relatively large number of blisters that are also capable of containing a large payload without any significant increase in the overall size of the device. The inhalation device of the present invention should also be much easier to make, assemble and operate as well as being cheaper to manufacture.

According to the invention, there is provided an inhaler comprising a housing to receive a strip of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, a mouthpiece through which a dose of medicament is inhaled by a user and, an actuator operable to sequentially move each blister into alignment with a blister piercing element, said actuator also being operable to cause the blister piercing element to puncture the lid of a blister such that, when a user inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it out of the blister and via the mouthpiece into the user's airway.

In a preferred embodiment, the actuator is pivotally mounted to the housing and may comprise an arm pivotally mounted to the housing at one end. The blister piercing element may depend from one side of said arm positioned so as to extend through the aperture in the housing in a closed position, in which the arm lies substantially against the housing, to pierce the lid of a blister aligned with the aperture.

Advantageously, the piercing element comprises at least two discrete piercing members operable to pierce a corresponding number of holes in a blister aligned with the blister piercing element.

Each piercing member may preferably comprise a central piercing blade and a pair of subsidiary piercing blades extending laterally across each end of the central

piercing blade. Conveniently, the central piercing blade and the subsidiary piercing blades each have a pointed tip, the tip of the central piercing blade extending beyond the tips of each of the subsidiary piercing blades. Ideally, the subsidiary piercing blades are parallel to each other and extend at right angles to the central piercing blade.

In a preferred embodiment, an opening is formed in the arm in the vicinity of each piercing member, at least one of said openings forming an airflow inlet into a blister and, at least one other of said openings forming an airflow outlet from a blister. Conveniently, the subsidiary piercing blades upstand from the edge of said opening in the arm and the central piercing blade is extends across the opening and connect to each of the subsidiary piercing blades.

Advantageously, the mouthpiece is on the arm and extends in a direction opposite to the direction in which the piercing members extend, the openings in the arm being in communication with the inside of the mouthpiece. In a preferred embodiment, the mouthpiece, the arm and the piercing elements are integrally formed.

The mouthpiece preferably includes a primary chamber having an outside air inlet in communication, via the primary chamber, with the or each airflow inlet opening in the arm and, a secondary chamber in communication with the or each airflow outlet opening in said arm such that, when a user inhales through the mouthpiece, air is drawn through the or each airflow inlet opening into the blister via the outside air inlet and the primary chamber to entrain the dose in the airflow, said entrained dose passing through the or each airflow outlet openings into the secondary chamber of the mouthpiece from where it is carried into the user's airway.

The primary and secondary chambers within the mouthpiece may separated by a partitioning wall and at least one air bypass aperture may extend through the partitioning wall to communicate the primary chamber with the secondary chamber. As air can pass directly from the primary to the secondary chambers when a user inhales, in addition to passing through the blister, the effort required to inhale

through the mouthpiece is reduced.

The or each bypass aperture may be configured such that the airflow from the primary chamber into the secondary chamber through the or each bypass aperture and the airflow from the or each airflow outlet openings meet substantially at right angles to each other. As the flows meet at an angle, the degree of turbulence is increased which assists in the deagglomeration of the dose and the creation of an inhalable aerosol.

In a most preferred embodiment the inhaler includes an indexing mechanism including an indexing member that moves so as to move a blister into alignment with the blister piercing element. Most preferably, the indexing member is a wheel which rotates so as to move a blister into alignment with the blister piercing element. However, it is also envisaged that other arrangements are possible such as, for example, a mechanism that incorporates a sliding or reciprocating member.

Preferably, the indexing wheel is configured to rotate to move a blister into alignment with said blister piercing element in response to rotation of the actuator with respect to the housing in one direction, movement of the actuator in the same direction also being operable to puncture the lid of a blister aligned with the blister piercing element. As the indexing and piercing steps are carried out during the same stroke of the actuator, the inhaler is particularly easy to use. However, it will be appreciated that the inhaler can be configured so that indexing of the blister strip occurs when the actuator is pivoted in one direction and piercing of a blister occurs when it is rotated in the opposite direction.

Preferably the indexing wheel and the actuator include co-operating means thereon that engage when the actuator is rotated in one direction to cause rotation of the indexing wheel.

In one embodiment, the cooperating means comprise a set of ratchet teeth on the indexing wheel and a drive pawl on the actuator.

Advantageously, means depend from the housing to substantially prevent rotation of the indexing wheel other than by movement of the actuator in said one direction.

In one embodiment said means comprises a first resiliently deformable anti-rotation pawl on the housing that extends into one of said recesses in the indexing wheel, the actuator including means for deflecting the first anti-rotation pawl from the recess to permit rotation of the indexing wheel when the drive pawl engages with the ratchet teeth.

The actuator may include a drive plate and the means on the actuator for deflecting the first anti-rotation pawl comprises a release pin upstanding from the drive plate that engages with and resiliently deflects the pawl out of the recess to allow rotation of the indexing wheel.

The inhaler may also comprise a second resiliently deformable anti-rotation pawl on the housing and a cam member on the actuator, the cam member engaging with a cam surface on the second anti-rotation pawl when the first anti-rotation pawl is deflected out of a recess to prevent rotation of the indexing wheel through more than a predetermined angle.

The inhaler may include a cap attached to the housing pivotable between a closed position in which it covers the actuator and mouthpiece and an open position in which the actuator and mouthpiece are revealed to enable a user to inhale through the mouthpiece.

In another embodiment of the invention, the indexing wheel rotates to move a blister into alignment with the blister piercing element in response to rotation of the cap with respect to the housing from the open to the closed position. This embodiment simplifies the operation of the device even further by providing that the piercing and indexing steps are performed in response to opening and closing of the cap that locates over the mouthpiece.

Preferably, the cap and the actuator include co-operating means to couple the

actuator to the cap such that the actuator rotates relative to the housing in response to rotation of the cap between the open and closed positions.

The cooperating means may comprise a cam guide slot on the cap and a cam follower on the actuator slideably located within the cam guide slot. Ideally, the cam guide slot is shaped such that when the cap is rotated from its closed to its open position, the cam follower travels along the cam guide slot to rotate the actuator and cause the blister piercing member to pierce a blister aligned therewith the aperture and, when the cap is rotated from its open to its closed position, the cam travels back along the cam guide slot to cause the actuator to rotate in the opposite direction and withdraw the piercing member from the blister. Furthermore, the cam guide slot may be configured so that the actuator does not rotate until towards the end of the movement of the cap from its closed to its open position and rotates at the beginning of the movement of the cap from its open to its closed position.

In a preferred arrangement, the indexing wheel and the cap each include a toothed gear member mounted thereon engaged such that rotation of the cap between the open and closed positions causes rotation of the gear member on the indexing wheel.

A clutch member preferably couples the gear member on the indexing wheel to the indexing wheel such that the indexing wheel rotates together with the gear member coupled thereto when the cap is rotated from the open to the closed position to move a subsequent blister into alignment with the blister piercing element.

The housing advantageously includes a chamber to receive used blisters. The chamber may be covered by a lid attached to the housing which is openable to facilitate removal of a portion of used blisters from the blisters remaining in the device.

Preferably, a separating element is mounted on the housing which is operable to enable detachment of said portion of used blisters. The separating element preferably includes a resilient blister grip which is operable to press a blister strip

against the housing to facilitate separation of said portion from said remaining blisters.

The inhaler according to the invention may also incorporate a coiled strip of blisters, each having a puncturable lid and containing a dose of medicament for inhalation by a user, located in the housing.

According to the invention, there is also provided a method of using an inhaler according to the invention including the step of rotating the actuator to move a blister into alignment with a blister piercing element in the housing and to puncture the lid of a blister aligned with the blister piercing element and, inhaling through the mouthpiece to generate an airflow through the blister to entrain the dose contained therein and carry it through the aperture and via the mouthpiece into the user's airway.

The step of rotating the actuator may include the step of rotating it in a first direction to puncture the lid of a blister aligned with the blister piercing element and, once the inhalation step is complete, rotating it in a second direction to move a subsequent blister into alignment with the blister piercing element in the housing. Additionally, the step of rotating the actuator may comprise the step of rotating a cap coupled to the actuator.

Embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings, in which:-

FIGURE 1 is a perspective view of an inhaler according to an embodiment of the invention;

FIGURE 2 is a perspective view of the inhaler illustrated in Figure 1 with the cap open to reveal the mouthpiece and the actuator in a closed position;

FIGURE 3 is a perspective view of the inhaler illustrated in Figure 2 with the actuator in an open position;

FIGURE 4 is a perspective view of the inhaler shown in Figure 1 with a used blister chamber cover open;

FIGURE 5 is an exploded perspective view of the inhaler illustrated in Figures 1 to

4 also showing a coiled strip of blisters used with the device according to the invention;

FIGURE 6 is a rear cross-sectional view of the inhaler illustrated in Figures 1 to 5 with the actuator shown separately;

FIGURE 7 is a front cross-sectional view of the inhaler illustrated in Figure 6 in which the actuator is pivotally mounted to the housing;

FIGURE 8A and 8B shows the configuration of the piercing elements on the actuator and a small portion of a strip of blisters to illustrate the type of cut made therein by the piercing elements, respectively;

FIGURE 9 is a side sectional view of the mouthpiece and actuator during inhalation from a blister;

FIGURE 10A to 10C show a series of front cross-sectional views of the inhaler according to the invention with a blister strip located therein to show the path of used blisters from the housing;

FIGURE 11 is an exploded side cross-sectional view of an inhaler according to another embodiment of the invention;

FIGURE 12A and 12B are side cross-sectional views of the inhaler according to the second embodiment with the cap in the closed and open positions respectively;

FIGURE 13 shows a short portion of a strip of blisters for use in the inhaler according to any embodiment of the invention;

FIGURE 14A and 14B are perspective views of another embodiment of inhaler according to the present invention;

FIGURE 15A and 15B show a side cross-sectional view of the inhaler illustrated in Figure 14A and 14B with the actuator in a closed and open position respectively.

FIGURE 16 is another side cross-sectional view of the inhaler shown in Figure 14A and 14B;

FIGURE 17 is a side sectional view of the mouthpiece and actuator during inhalation from a blister;

FIGURE 18 shows an alternative configuration of piercing elements on the actuator according to any embodiment of the invention, and

FIGURE 19A shows the airflow into the blister using the piercing elements of Figure 8A and Figure 19B shows the airflow into the blister using the piercing element of Figure 18.

A first embodiment of the inhaler according to the invention will be described with reference to Figures 1 to 10. This embodiment provides a simple, easy to use inhalation device that indexes and pierces a blister using the same actuator. Furthermore, the actuator both indexes and pierces a blister during the same stroke or direction of rotation of the actuator.

Referring now to the drawings, there is shown in Figure 1 an inhaler 1 according to a first embodiment of the invention comprising a housing 2 to which is pivotally mounted an actuator 3. A cap 4 is integrally hinged to the top edge of the housing 2 and is pivotable between a closed position, as shown in Figure 1, to an open position, as shown in Figure 2, to gain access to a mouthpiece 5 integrally formed with and upstanding from the actuator 3. The cap 4 completely covers and protects the mouthpiece 5 when closed and prevents contamination thereof or the possible ingress of dirt into the housing 2 which could otherwise be inhaled when the device is used.

The inhaler 1 is intended for use with a strip 6 of moisture proof blisters (see Figure 13) each containing a pre-measured dose of powdered medicament for inhalation. Each blister 6a in the strip 6 comprises a generally hemispherically shaped pocket 6b and a flat puncturable lid 6c permanently heat sealed to the pocket 6b to hermetically seal the dose therein. The strip 6 is preferably manufactured from foil laminate or a combination of foil laminate, such as aluminium, and plastics material.

The actuator 3 comprises a lever arm 7 having one end pivotally mounted to the housing 2 to enable it to rotate from a closed position shown in Figures 1, 2 and 4 into an open position shown in Figure 3. As can be seen from Figure 3, the housing 2 has an aperture 8 therein to receive a pair of piercing members 9 that extend from the lever arm 7 when the actuator 3 is in a closed position and penetrate the lid 6c of a blister located within the housing 2 immediately behind the aperture 8.

The shape of the piercing members 9 will now be described with reference to Figure 8A. This is important because the openings that are made in the lid 6c of a blister 6a

must be of a sufficient cross-sectional area and shape to promote the free-flow of air through the blister 6a and to ensure that all of the internal volume of the blister 6a is swept by the airflow and consequently that all, or substantially all, of the dose is entrained and carried out of the blister 6a. Each piercing member 9 comprises a generally "H" shaped element having a flat blade-like central tooth 10 and a pair of flat blade-like end teeth 11 extending laterally across each end of the central tooth 10. The central and side teeth 10,11 taper to a point in the centre of each tooth 10,11. The height of the mid-point of the side teeth 11 is such that the points of the side teeth 11 are at the same height as the edges of the central tooth 10 and the top edges of each tooth 10,11 are sharpened to enable them to easily penetrate and cut the lid 6c of a blister 6a.

As can be seen in Figure 8A, the side teeth 11 of each piercing member 9 upstand from opposite edges of an aperture 12 in the lever arm 7 to enable the flow of air through the arm 7 into and out of the blister 6b via the holes made in the lid 6c of the blister 6b with the piercing members 9. The central tooth 10 is attached to, and is supported between, each of the side teeth 11 and extends across the aperture 12 and so is not attached directly to the lever arm 7.

Figure 8B illustrates a short section of a strip 6 of blisters 6a to show the shape and size of the openings that each of the piercing elements 9 described with reference to Figure 8A cut in the lid 6c of a blister 6b. The point of each of the central teeth 10 penetrate the lid 6c first (point A in Figure 8B) and, as they enter the blister 6a, two linear cuts are made by each of them, as indicated by arrows "B". When the side teeth 11 penetrate the blister 6a, further lateral cuts are made at each end of the linear cuts and perpendicular thereto, as indicated by arrows "C". These cuts have the effect of creating flaps 12a which are folded back into the blister 6a as the piercing elements 9 enter it. These piercing members 9 are capable of forming openings which extend to over 30 to 50% of the surface area of a lid 6c of a blister 6a.

As shown in Figure 4, a cover 13 is pivotally attached to the side of the housing 2 and encloses a space to receive used blisters 6d that are fed into said space through

a slot 14 in the wall of the housing 2. The space within the cover 13 is large enough to accommodate only a few used blisters 6d therein and so a resiliently flexible blister grip 15 extends from the housing 2 and facilitates removal of some of the used blisters 6d from the blisters 6 that remain in the housing 2. To remove a section of used blisters 6d, the blister grip 15 is pressed against the strip 6 to sandwich it between the blister grip 15 and the sidewall of the housing 2. The visible section of used blisters 6d can then be grasped in the hand, torn off and discarded without inadvertently placing undue force on the remaining part of the blister strip 6 that would tend to pull it out of the housing 2. Figures 10A to 10C show three front cross-sectional views through the inhaler 1. In Figure 10A, there are no empty blisters 6d protruding through the slot 14. In Figure 10B, the device has been activated twice more and so two empty blisters 6d have now passed through the slot 14. In Figure 10C, the blister grip 15 has been pressed against the housing 2 in the direction of arrow "A" to enable the two empty blisters 6d to be detached by pulling them in the direction of arrow "B".

It will be appreciated that a cover 13 is not essential and the used blisters 6d may be removed as soon as they emerge from the aperture 14 in the wall of the housing 2. In another embodiment, the inhaler 1 may be provided with a cutting implement (not shown) such as a blade or serrations against which the section of used blisters 6d to be removed may be pressed to facilitate their detachment. In a preferred arrangement, a blade may be mounted to and extend from the blister grip 15 so that when it is pressed against the housing 2 it cuts the strip 6d located between the blister grip 15 and the housing 2. In yet another embodiment, the inhaler 1 may incorporate a larger chamber possibly with a take-up spool around which the used blister strip 6d may be wound so that it can be removed as a whole from the device and so avoid the need to detach sections of the strip 6d as each short section of blisters 6a are used up. However, in order to keep the device as small as possible, it is preferable to provide an arrangement in which at least some of the used blisters 6d can easily be removed from the device whilst unused blisters remain in it.

Referring now to Figure 5, the housing 2 comprises a generally cylindrically shaped chamber 20 to receive a coiled or wound strip of blisters 6 each containing a pre-

measured dose of medicament to be delivered using the inhaler 1. The leading end 6e of the strip 6 is received in a blister feed inlet path 21 which opens up into a generally cylindrical cavity 22 adjacent to and in communication with the aperture 8 in the housing 2 and in which is rotatably received an indexing wheel 23. A used blister feed outlet path 30 extends from the cylindrical cavity 22 and leads to the aperture 14 in the wall of the housing 2.

The chamber 20 has a cover (not shown in Figure 5) that forms part of the housing 2. Preferably, the cover is removably attached to the remainder of the housing 2 to enable access to the inside of the inhaler 1 to be obtained to enable a fresh strip 6 of blisters to be inserted therein. However, it is envisaged that the device could form a disposable unit in which case a strip of blisters 6 could be mounted in the device during assembly and the cover permanently attached so that once the strip has been exhausted, the whole device is thrown away. The simplicity of the construction of the device and the relatively few separate components make the device very cheap to manufacture and so a disposable unit is a viable proposition.

The indexing wheel 23 is a generally cylindrically shaped member with a set of blister receiving grooves or recesses 24 extending longitudinally along its outer surface parallel to its axis of rotation. Each groove 24 is shaped so as to receive a blister 6a therein as the indexing wheel 23 rotates, as will be explained in more detail below. The recesses 24 are spaced at a pitch which is equal to the distance "d" between the centre lines of a pair of blisters, as indicated in Figure 13, so that as the indexing wheel 23 rotates, a strip 6 extending through the blister feed path 21 and over the indexing wheel 23 is pulled so that a blister 6a locates in the recess 24 of the indexing wheel 23 situated immediately opposite the aperture 8, as will be explained in more detail below. To enable the indexing wheel 23 to rotate in response to rotation of the actuator 3 in one direction, ratchet teeth 25 are formed on one end face thereof for cooperation with the actuator 3 as will shortly be explained, each tooth 25 comprising an arcuately shaped ramp section 26 and a shoulder 27. The indexing wheel 23 is a close fit in the cylindrical cavity 22 so that the strip 6 is securely held by the indexing wheel 23 and each blister 6a is snugly received and held in the recess 24 opposite the aperture 8 whilst allowing for

rotation of the indexing wheel 16 to feed the strip of blisters 6 through the device. As the indexing wheel 23 rotates, the used blisters 6d are fed out of the cavity 22 down the used blister feed path 30 and through the slot 14 out of the housing 2.

A drive plate 27a depends from a longitudinal edge of the lever arm 7 and carries a drive pawl 28 thereon for cooperation with the ratchet teeth 25 on the indexing wheel 23 during rotation of the actuator 3 from the open to the closed position. The drive pawl 28 is integrally formed in the drive plate 27a by cutting a U-shaped slot therein to form a resiliently deformable tab 29 from which the drive pawl 28 upstands.

The mouthpiece 5 is integrally formed with the lever arm 7 of the actuator 3 and upstands from one side thereof opposite to the side from which the piercing members 8 extend. The interior of the mouthpiece 5 can be seen from the cross-sectional view of Figure 9 and is divided into a primary and a secondary chamber 31,32 by a partitioning wall 33. An outside air inlet orifice 34 in the sidewall of the mouthpiece 5 close to where it joins or becomes the lever arm 7 is in communication with the primary chamber 31. The primary chamber 31 is also in communication with one of the apertures 11a in the lever arm 7 which is formed in the vicinity of a piercing member 9. The secondary chamber 32 makes up the main internal volume of the mouthpiece 5 and is in communication with the other aperture 11b in the lever arm 7. A bypass aperture 35 extends through the partitioning wall 33 to communicate the primary chamber 31 with the secondary chamber 32 for reasons that will become apparent.

The path of the blister strip 6 through the device and the way in which it is disposed within the chamber 20 can be most clearly seen in Figure 7. It will be appreciated that the coils of the blister strip 6 are loosely wound in the chamber 20 so that the blister strip 6 will unwind in response to a pulling force applied to the leading edge 6e of the strip by the indexing wheel 23 as the indexing wheel 23 rotates.

To prevent rotation of the indexing wheel 23, other than due to rotation of the actuating member 3, the housing 2 is provided with an integrally formed resiliently

flexible arm 36 carrying an anti-rotation pawl 37 that normally locates in one of the recesses of the indexing wheel 23 which is not occupied by a blister 6a, as shown in Figure 6. Engagement of the pawl 37 with the indexing wheel 23 prevents the indexing wheel 23 from rotating. A release pin 38 upstands from the drive plate 27a which engages the arm 37 to push the pawl 38 out of the recess to allow rotation of the indexing wheel 23 when the actuator 3 approaches its fully open position.

When the pawl 38 is deflected from the recess 24, the blister strip 6 could be pulled from the housing 2. To prevent this, a second resiliently deformable anti-rotation pawl 39 is provided on the housing 2. The second anti-rotation pawl 39 has a cam surface 40 thereon which is engaged by a cam member 41 on the actuator 3 when the first anti-rotation pawl 37 is pushed out of the recess 24 of the indexing wheel 23. The second anti-rotation pawl 39 is therefore locked into position and protrudes into another recess 17 of the indexing wheel 23. This prevents the indexing wheel 23 from rotating by more than approximately 45 degrees and so the strip 6 can only be pulled through the device by about half a blister width.

It will be appreciated from the foregoing that the inhalation device according to this embodiment of the invention has a very simple construction with relatively few components.If the cap 4 is integrally formed with the housing 2 in a single moulding and the actuator 3 is formed together with the mouthpiece 5, the piercing elements 9, the drive plate 27a and the drive pawl 28 in another moulding, the device can be formed from as few as 4, 5 or 6 moulded plastic parts.

Operation of the inhaler 1 will now be described. When the inhaler 1 is not in use, the cap 4 and the lever arm 7 are both in a closed position in which the cap 4 covers the mouthpiece 5 and the lever arm 7 lies generally against the side of the housing 2 with the piercing members 9 extending through the aperture 8 in the housing 2 and into a previously exhausted blister 6d lying immediately below the aperture 8 and constrained in the uppermost recess 24 of the indexing wheel 23 adjacent to the aperture 8. The first and second anti-rotation pawls 37,39 prevent rotation of the indexing wheel 23 in either direction and so locate the blister in position.

When the cap 4 is opened, the lever arm 7 can be pivoted into the position shown in Figure 3. As the lever arm 7 pivots, the drive pawl 28 on the drive plate 27a rides up the ramp section 26 forming one of the ratchet teeth on the end of the indexing wheel 23 and so no rotation of the indexing wheel 23 occurs. Once a fully open position has been reached, as shown in Figure 3, the drive pawl 28 has reached the end of the ramp section 26 and drops down against the face of a corresponding shoulder 27 so that as the actuator 3 is rotated back in the opposite direction from the open to the closed position, engagement between the drive pawl 28 and the shoulder 27 causes the indexing wheel 23 to rotate. It will be appreciated that if the lever arm 7 is not opened to its fullest extent before being returned to its closed position, the indexing wheel 23 will not rotate because the drive pawl 28 will not have dropped down to engage a shoulder 27 at the top of the ramp section 26.

Just before the lever arm 7 reaches its fully open position, the release pin 38 on the drive plate 27a engages with the arm 36 from which the first anti-rotation pawl 37 extends and deflects it so that the anti-rotation pawl 37 moves out of the recess 24 in the indexing wheel 23 so that the indexing wheel 23 can rotate and the strip 6 can be indexed when the lever arm 7 is rotated in the opposite direction. At the same time, the cam member 41 engages with the cam surface 40 of the second anti-rotation pawl 39 and locks it into position to ensure that the strip 6 cannot be pulled from the inhaler 1 by more than approximately half the width of a blister 6b.

As the lever arm 7 is pivoted back into its closed position, the indexing wheel 23 is rotated through 90 degrees as a result of engagement between the drive pawl 28 and the shoulder 27 on the indexing wheel 23. Whilst the lever arm 7 is rotated back into its closed position, the anti-rotation pawls 37,39 have returned to their original positions locking the indexing wheel 23 in place. This rotation of the indexing wheel 23 brings the next blister 6b into position immediately below the aperture 8 in the housing 2.

In the final stage of the return stroke of the lever arm 7 back to its closed position, the piercing members 9 pass through the aperture 8 in the housing 2 and penetrate the lid 6c of the blister 6a that has just been moved into position by the indexing

wheel 23. The dose is now ready for inhalation, as will now be described.

When a user inhales through the mouthpiece 5, a low pressure region is created in the secondary chamber 32 causes air to be drawn through the blister 6a from the outside air inlet 34 via the primary chamber 31 and the airflow opening 11a in the lever arm 7, as indicated by arrows marked "X" in Figure 9. This airflow through the blister 6b entrains the dose contained therein which is carried into the secondary chamber 32 and from there into the patient's airway.

The turbulent airflow generated through the aperture 11b in the lever arm 7 around the piercing element 9 helps to deagglomerate the dose and create a respirable aerosol. The air bypass orifice 35 in the partitioning wall 33 between the primary and secondary chambers 31,32 reduces the overall pressure drop across the device and so makes it easier for the patient to inhale. It also increases turbulence in the secondary chamber 32. In a particularly preferred arrangement, the bypass orifice 35 is situated so that the airflow therethrough, indicated by arrow "Y" in Figure 6, meets the airflow entering the secondary chamber 32 from the blister at a tangent or right angle so as to create a cyclonic effect or increase the airflow turbulence to assist deagglomeration.

Once the device has been used a number of times, the side cover 13 may be opened and the visible section 6d of used blisters may be detached from those that remain within the device as has already been explained.

A second embodiment of the inhaler according to the invention will now be described with particular reference to Figures 11 and 12. In this embodiment, the actuator is coupled to the cap covering the mouthpiece so that a blister is pierced when the cap is opened and indexed to move the next unused blister into position beneath the aperture in the housing when the cap is closed. This provides a device which is very simple to operate as the user does not have to open the cap before pivoting the actuator to index and pierce a blister.

Referring to the exploded view of Figure 11, the inhaler 1 is similar to the device

described with reference to the first embodiment except that the ratchet teeth on the indexing wheel 23 have been replaced with a toothed gearwheel 40 which is attached to the indexing wheel via a one-way or clutch mechanism (not shown) so that the indexing wheel 23 will rotate together with the gearwheel 40 in only one direction of rotation, the gearwheel being free to rotate in the opposite direction relative to the indexing wheel 23.

The actuator has a similar construction to the actuator 3 of the first embodiment and comprises a lever arm 7 with the mouthpiece 5 and piercing elements 9 upstanding from opposite sides thereof. However, in this embodiment, the actuator 3 is not directly pivoted by the user. Instead, a cam pin 41 protrudes from the side of the lever arm 7 adjacent to the remote end opposite the end pivotally mounted to the housing 2. The cam pin 41 is located in a cam track or groove 42 formed on the inside surface of a cap 43 pivotally attached to the side of the housing 2 at the same end but spaced from the location at which the actuator 3 is pivotally attached to the housing 2. The cap 43 also carries a toothed gearwheel 44 attached thereto for rotation together with the cap 43 which lies in meshing engagement with the gearwheel 40 on the indexing wheel 23.

As has already been mentioned with reference to the first embodiment, the inhalation device according to the second embodiment also has a very simple construction with relatively few components. For example, if the gearwheel 44 is integrally formed together with the cap and the actuator 3 is formed together with the mouthpiece 5 and the piercing elements 9, the whole device can be formed from as few as 4, 5 or 6 moulded plastic parts.

Due to the small number of parts and simplicity of the device, there is more storage room within the device for blisters thereby reducing the frequency that it must be re-filled or replaced. It is intended that the devices of the present invention will have a capacity to hold between 1 and more than 100 doses although preferably it will be capable of holding between 1 and 60 doses and most preferably between 30 and 60 doses. The payload of each blister may be between 1μg and 100mg. However, preferably, the payload is in the region of 1mg to 50mg and most

preferably between 10mg and 20mg. It will also be apparent that due to its simplicity, the device may be disposable once all the blisters contained therein have been used up. In this case, the housing may be formed as a permanently sealed enclosure to prevent tampering.

Operation of the inhaler according to the second embodiment will now be described with particular reference to Figures 12A and 12B. As can be seen in Figure 12A, when the cap 43 is closed, the piercing elements 9 on the actuator 3 are held clear from the aperture 8 in the housing 2 by means of the cam pin 41 located in the cam track 42 in the cap 43. The cam track 42 is preferably shaped so that the cap 43 can be initially pivoted relative to the housing 2 by at least 90 degrees without any movement of the actuator 3 occurring thereby allowing inspection or cleaning of the mouthpiece 5 without piercing of a blister 6a. However, when the cap 43 is rotated relative to the housing 2 beyond 90 degrees, the cam pin 41 is guided by the track 42 causing the actuator 3 to pivot into a position shown in Figure 12B in which the piercing elements 9 extend through the aperture 8 in the housing 2 and penetrate a blister 6b situated immediately behind the aperture 8 within the housing 2. At this stage, the dose may be inhaled through the mouthpiece 5.

As the cap 43 opens the gearwheel 40 rotates due to engagement with the gearwheel 44 on the cap 43. However, because of the one-way clutch mechanism, the indexing wheel 23 does not rotate as the cap 43 is opened and the gearwheel 40 is rotated in this first direction. However, once the cap 43 is rotated in the opposite direction, i.e. from the open to the closed position following inhalation, drive of the gearwheel 40 is transferred to the indexing wheel 23 so that it rotates and moves the next blister 6a into alignment with the aperture 8. It will be appreciated that during initial movement of the cap 43 from its open to its closed position, the actuator 3 will first be pivoted, due to the engagement of the cam pin 41 in the cam track 42, so that the piercing elements 9 are lifted out of the aperture 8 and back into the position shown in Figure 12A.

It is envisaged that, in either embodiment, an opening or window could be provided in the housing 2 and a dose number printed on each blister 6a readable through the

opening or window so that the user can monitor the number of doses that have been used or that remain in the device. This avoids the need for a complicated dose counting mechanism often found in conventional devices. Alternatively, the housing 2 could be wholly or partially formed from a transparent material so that the number of blisters 6 remaining in the device can clearly be seen through the walls of the housing 2.

As shown in the Figure 13, the blister strip 6 provided for use with the inhaler 1 of the invention may be provided with serrations or cut-lines 50 to facilitate the separation of the blisters 6a from each other. Alternatively, or in addition to the cut-lines, the edge of the blister strip 6 may be provided with notches 51 between each blister 6a to make the strip easier to tear.

Another embodiment of the device will now be described with reference to Figure 14A to 19. This version of the device has the particular benefit of being small in size relative to the number of blisters that it may contain. Instead of placing the indexing wheel in its own cavity adjacent to the aperture in the housing through which the piercing elements extend, the indexing wheel is formed integrally with the hinge which pivotally connects the actuating lever to the housing. This frees up more space within the housing for blister storage. As can be seen from the drawings, the device is able to contain a coil of at least 60 blisters.

Referring first to Figure 14A and 14B, there is shown two perspective views of the inhaler according to this embodiment. The inhaler 50 is similar to the inhaler 1 of the first embodiment and comprises a housing 51 having an actuator 52 in the form of a lever arm 53 pivotally mounted to the housing 51 at one end. Piercing elements 54 extend from the lever arm 53 and locate in an aperture 55 in the housing when the actuator 52 is in a closed position with the lever arm 53 lying substantially against the housing 51, as shown in Figure 14A. A cap 56 is pivotally attached to the housing 51 and is operable to cover the mouthpiece 57 when the inhaler is not in use.

As with the first and second embodiments, the mouthpiece 57 is integral with the

lever arm 53 although it has a triangular or semicircular section against which the lips can be placed, as opposed to a tubular section which is placed in the mouth. The shape of the mouthpiece and the airway construction within it is illustrated in the cross-sectional view of Figure 18. It will be appreciated that the airway construction is very similar to the construction of the airway described with reference to the first and second embodiments and so no further description of it will be made here. However, it will be appreciated that because the indexing wheel is now located away from the region where the blister is pierced, the blister to be pierced is now supported in a blister support block 58 (see Figure 17).

The device 50 includes an indexing wheel (not shown) incorporating a ratchet mechanism as has already been described with reference to the first and second embodiments, except that in this embodiment the indexing wheel has been made integral with the hinge about which the lever arm 53 pivots so that it rotates about the same axis as the lever arm 53.

When the cap 56 has been opened and the lever is pivoted from its closed position (as shown in Figure 14A) into its open position (as shown in Figure 14B), the indexing wheel rotates together with the lever due to engagement between a ratchet mechanism between the indexing wheel and the lever 53 and so draws a blister into alignment with the aperture 55 and locates in the blister support block 58. However, when the lever is returned to its closed position, the indexing wheel does not rotate due to the ratchet mechanism so the blister strip remains stationary. A second ratchet connection between the indexing wheel and the housing prevents backwards rotation the indexing wheel. During the final part of the return stroke, the piercing elements 54 extend through the aperture 55 and pierce the lid of the aligned blister. The dose is now ready for inhalation through the mouthpiece 57.

As described with reference to the previous embodiments, the device may incorporate a chamber to receive used blisters. However, this is not essential and the used blisters may simply be fed out of the device. A serrated cutting edge 59 (see Figure 16) may extend from the aperture against which used blisters may be torn off by pulling them against the serrated edge in the direction indicated by the

arrow in the drawing. It will be noted that the strip is prevented from being pulled out of the device by the piercing element which is located in a blister and secures it in position.

It will be appreciated that any piercing element arrangement may be used including solid or hollow pins as well as piercing blades. It is desirable to include features that enhance the flow of air into the blister to aid entrainment and deagglomeration by, for example, introducing a swirling airflow into the blister. One particular arrangement of piercing element 60 which may be employed with any embodiment of the invention and which allows a freer flow of air into the blister will now be described with reference to Figures 18 and 19.

As can be seen from Figure 18, the lever arm has a pair of apertures 61 therein for the flow of air into the blister and the flow of air together with the dose out of the blister. Each piercing element 60 comprises a pair of side piercing members 62 spaced from each other and configured so as to form a bridge over the aperture 61. A pointed central cutting member 63 extends between and connects each of the side piercing members 62 together. The side piercing members 62 are inwardly inclined toward each other so that the central piercing member 63 has diamond shape in side profile. As shown in Figure 19B, this open construction allows more air to flow around the sides of the blister in comparison with the piercing element arrangement of Figure 8A, as the side teeth restrict airflow into the blister (as shown in Figure 19A).

Many modifications and variations of the invention falling within the terms of the following claims will be apparent to those skilled in the art and the foregoing description should be regarded as a description of the preferred embodiments of the invention only.

## Claims

1. An inhaler comprising a housing to receive a strip of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, a mouthpiece through which a dose of medicament is inhaled by a user and, an actuator operable to sequentially move each blister into alignment with a blister piercing element, said actuator also being operable to cause the blister piercing element to puncture the lid of a blister such that, when a user inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it out of the blister and via the mouthpiece into the user's airway.

2. An inhaler according to claim 1, wherein the actuator is pivotally mounted to the housing.

3. An inhaler according to claim 1 or claim 2, wherein the actuator comprises an arm pivotally mounted to the housing at one end.

4. An inhaler according to claim 3, wherein the blister piercing element depends from one side of said arm positioned so as to extend through an aperture in the housing in a closed position, in which the arm lies substantially against the housing, to pierce the lid of a blister aligned with the blister piercing element.

5. An inhaler according to claim 3 or 4, wherein the piercing element comprises at least two discrete piercing members operable to pierce a corresponding number of holes in a blister aligned with the blister piercing element.

6. An inhaler according to claim 5, wherein each piercing member comprises a central piercing blade and a pair of subsidiary piercing blades extending laterally across each end of the central piercing blade.

7. An inhaler according to claim 6, wherein the central piercing blade and the subsidiary piercing blades each have a pointed tip, the tip of the central piercing

blade extending beyond the tips of each of the subsidiary piercing blades.

8. An inhaler according to any of claims 5 to 7, wherein an opening is formed in the arm in the vicinity of each piercing member, at least one of said openings forming an airflow inlet into a blister and, at least one other of said openings forming an airflow outlet from a blister.

9. An inhaler according to claim 8, wherein the mouthpiece is on the arm and extends in a direction opposite to the direction in which the piercing members extend, the openings in the arm being in communication with the inside of the mouthpiece.

10. An inhaler according to claim 8 or claim 9, wherein the mouthpiece includes a primary chamber having an outside air inlet in communication, via the primary chamber, with the or each airflow inlet opening in the arm and, a secondary chamber in communication with the or each airflow outlet opening in said arm such that, when a user inhales through the mouthpiece, air is drawn through the or each airflow inlet opening into the blister via the outside air inlet and the primary chamber to entrain the dose in the airflow, said entrained dose passing through the or each airflow outlet openings into the secondary chamber of the mouthpiece from where it is carried into the user's airway.

11. An inhaler according to claim 10, wherein the primary and secondary chambers within the mouthpiece are separated by a partitioning wall.

12. An inhaler according to claim 11, wherein at least one air bypass aperture extends through the partitioning wall to communicate the primary chamber with the secondary chamber.

13. An inhaler according to claim 12, wherein the or each bypass aperture is configured such that the airflow from the primary chamber into the secondary chamber through the or each bypass aperture and the airflow from the or each airflow outlet openings meet substantially at right angles to each other.

14. An inhaler according to any preceding claim, comprising an indexing mechanism including an indexing member that moves so as to pull a blister into alignment with the blister piercing element.

15. An inhaler according to claim 14, wherein the indexing member comprises an indexing wheel that rotates to move a blister into alignment with the blister piercing element.

16. An inhaler according to claim 14, wherein the indexing wheel is configured to rotate to move a blister into alignment with the blister piercing element in response to rotation of the actuator with respect to the housing in one direction, movement of the actuator in the same direction also being operable to puncture the lid of a blister aligned with the blister piercing element.

17. An inhaler according to claim 16, wherein the indexing wheel and the actuator include co-operating means thereon that engage when the actuator is rotated in one direction to cause rotation of the indexing wheel.

18. An inhaler according to claim 17, wherein the cooperating means comprises a set of ratchet teeth on the indexing wheel and a drive pawl on the actuator.

19. An inhaler according to any of claims 15 to 18, wherein the indexing wheel includes a plurality of recesses therein extending parallel to the axis of the wheel.

20. An inhaler according to any of claims 15 to 18, wherein the indexing wheel and actuator are coaxially mounted for rotation about the same axis.

21. An inhaler according to any of claims 15 to 20, including means to substantially prevent rotation of the indexing wheel other than by movement of the actuator in said one direction.

22. An inhaler according to claim 21, wherein said means comprises a first

resiliently deformable anti-rotation pawl that extends into one of said recesses in the indexing wheel from the housing, the actuator including means for deflecting the first anti-rotation pawl from the recess to permit rotation of the indexing wheel when the drive pawl engages with the ratchet teeth.

23. An inhaler according to claim 22, wherein the actuator includes a drive plate and the means on the actuator for deflecting the first anti-rotation pawl comprises a release pin upstanding from the drive plate that engages with and resiliently deflects the pawl out of the recess to allow rotation of the indexing wheel.

24. An inhaler according to claim 22 or claim 23, wherein the means on the actuator comprises a second resiliently deformable anti-rotation pawl on the housing and a cam member on the actuator, the cam member engaging with a cam surface on the second anti-rotation pawl when the first anti-rotation pawl is deflected out of a recess to prevent rotation of the indexing wheel through more than a predetermined angle.

25. An inhaler according to claim 15, including a cap attached to the housing pivotable between a closed position in which it covers the actuator and mouthpiece and an open position in which the actuator and mouthpiece are revealed to enable a user to inhale through the mouthpiece.

26. An inhaler according to claim 25, wherein the indexing wheel rotates to move a blister into alignment with the blister piercing element in response to rotation of the cap with respect to the housing from the open to the closed position.

27. An inhaler according to claim 26, wherein the cap and the actuator include co-operating means to couple the actuator to the cap such that the actuator rotates relative to the housing in response to rotation of the cap between the open and closed positions.

28. An inhaler according to claim 27, wherein the cooperating means comprises

a cam guide slot on the cap and a cam follower on the actuator slideably located within the cam guide slot.

29. An inhaler according to claim 28, wherein the cam guide slot is shaped such that when the cap is rotated from its closed to its open position, the cam follower travels along the cam guide slot to rotate the actuator and cause the blister piercing element to pierce a blister aligned therewith and, when the cap is rotated from its open to its closed position, the cam travels back along the cam guide slot to cause the actuator to rotate in the opposite direction and withdraw the blister piercing element from the blister.

30. An inhaler according to claim 29, wherein the cam guide slot is configured so that the actuator does not rotate until towards the end of the movement of the cap from its closed to its open position and rotates at the beginning of the movement of the cap from its open to its closed position.

31. An inhaler according to claim 30, wherein the indexing wheel and the cap each include a toothed gear member mounted thereon engaged such that rotation of the cap between the open and closed positions causes rotation of the gear member on the indexing wheel.

32. An inhaler according to claim 31, wherein a clutch member couples the gear member on the indexing wheel to the indexing wheel such that the indexing wheel rotates together with the gear member coupled thereto when the cap is rotated from the open to the closed position to move a subsequent blister into alignment with the blister piercing element.

33. An inhaler according to any preceding claim, wherein the housing includes a chamber to receive used blisters.

34. An inhaler according to claim 33, wherein the chamber is covered by a lid attached to the housing which is openable to facilitate removal of a portion of used blisters from the blisters remaining in the device.

35. An inhaler according to claim 34, including a separating element on the housing operable to enable detachment of said portion of used blisters.

36. An inhaler according to claim 35, wherein the separating element includes a resilient blister grip which is operable to press a blister strip against the housing to facilitate separation of said portion from said remaining blisters.

37. An inhaler according to any preceding claim incorporating a coiled strip of blisters, each having a puncturable lid and containing a dose of medicament for inhalation by a user, located in the housing.

38. An inhaler according to claim 37, wherein the strip includes a frangible cut line between each blister to facilitate detachment of a blister from an adjacent blister along said line.

39. An inhaler according to claim 37 or claim 38, wherein the strip includes a notch to facilitate tearing of the strip between each blister.

40. An inhaler according to any of claims 37 to 39, wherein the coiled strip carries between 30 and 60 blisters and each blister has a dose payload of between 10 and 20mg.

41. An inhaler according to any preceding claim formed from no more than four moulded components.

42. An inhaler according to any of claims 1 to 40, formed from no more that five moulded components.

43. An inhaler according to any of claims 1 to 40 formed from no more than six moulded components.

44. An inhaler according to any preceding claim wherein the housing is wholly or

partially formed from a transparent material.

45. A method of using an inhaler according to any of claims 1 to 44, including the step of rotating the actuator to move a blister into alignment with the blister piercing element and to puncture the lid of an aligned blister, inhaling through the mouthpiece to generate an airflow through the blister to entrain the dose contained therein and carry it via the mouthpiece into the user's airway.

46. A method according to claim 45, wherein the step of rotating the actuator includes the step of rotating it in a first direction to puncture the lid of a blister aligned with the blister piercing element and, once the inhalation step is complete, rotating it in a second direction to move a subsequent blister into alignment with the blister piercing element.

47. A method according to claim 46, wherein the step of rotating the actuator comprises the step of rotating a cap coupled to the actuator.

48. An inhaler substantially as hereinbefore described with reference to the accompanying drawings.

**Abstract**

**Inhaler**

An inhaler is disclosed. It comprises a housing to receive a strip of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, a mouthpiece through which a dose of medicament is inhaled by a user and, an actuator operable to sequentially move each blister into alignment with a blister piercing element. The actuator is also operable to cause the blister piercing element to puncture the lid of a blister such that, when a user inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it out of the blister and via the mouthpiece into the user's airway.

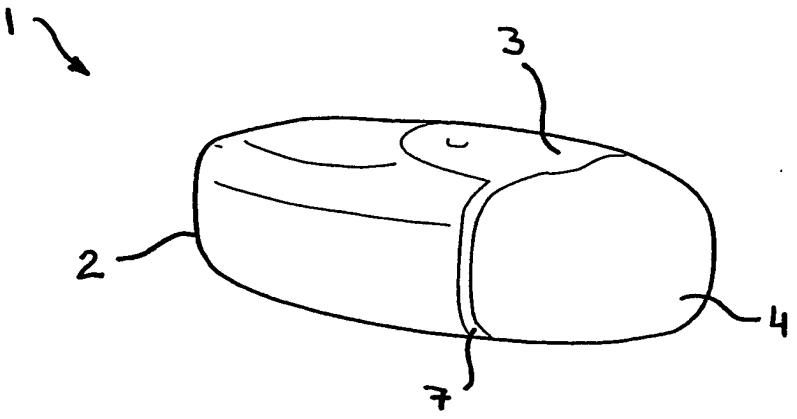


FIGURE 1

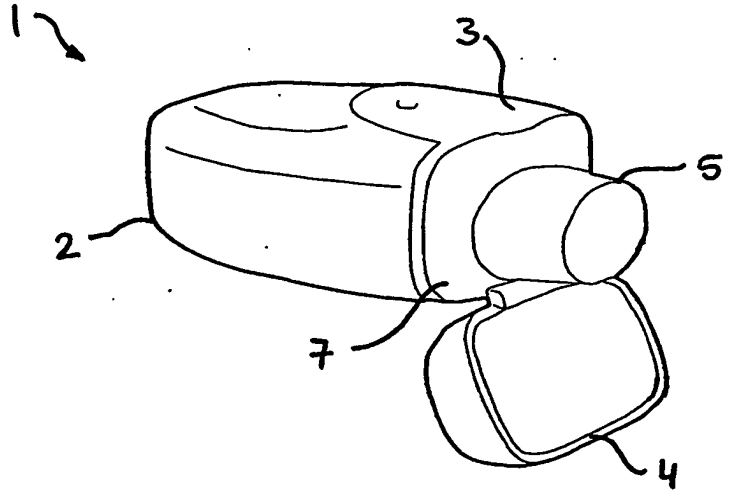


FIGURE 2

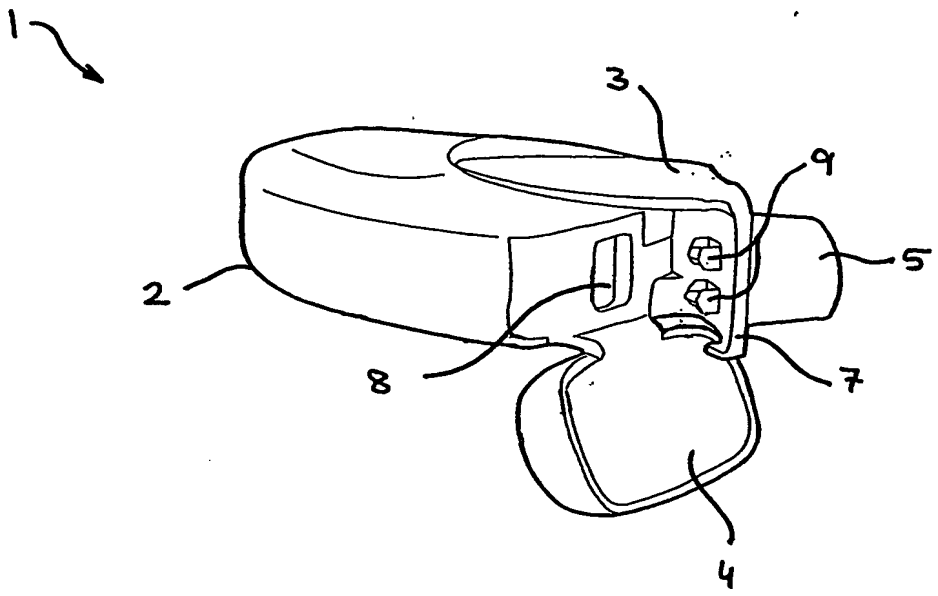


FIGURE 3

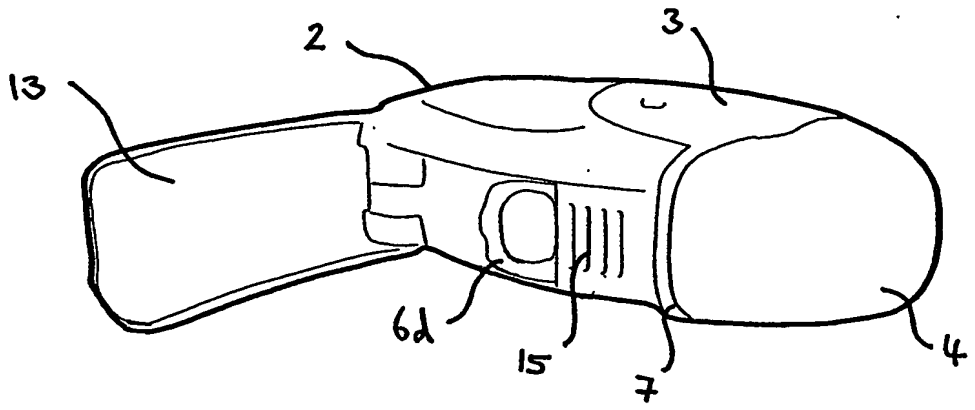


FIGURE 4

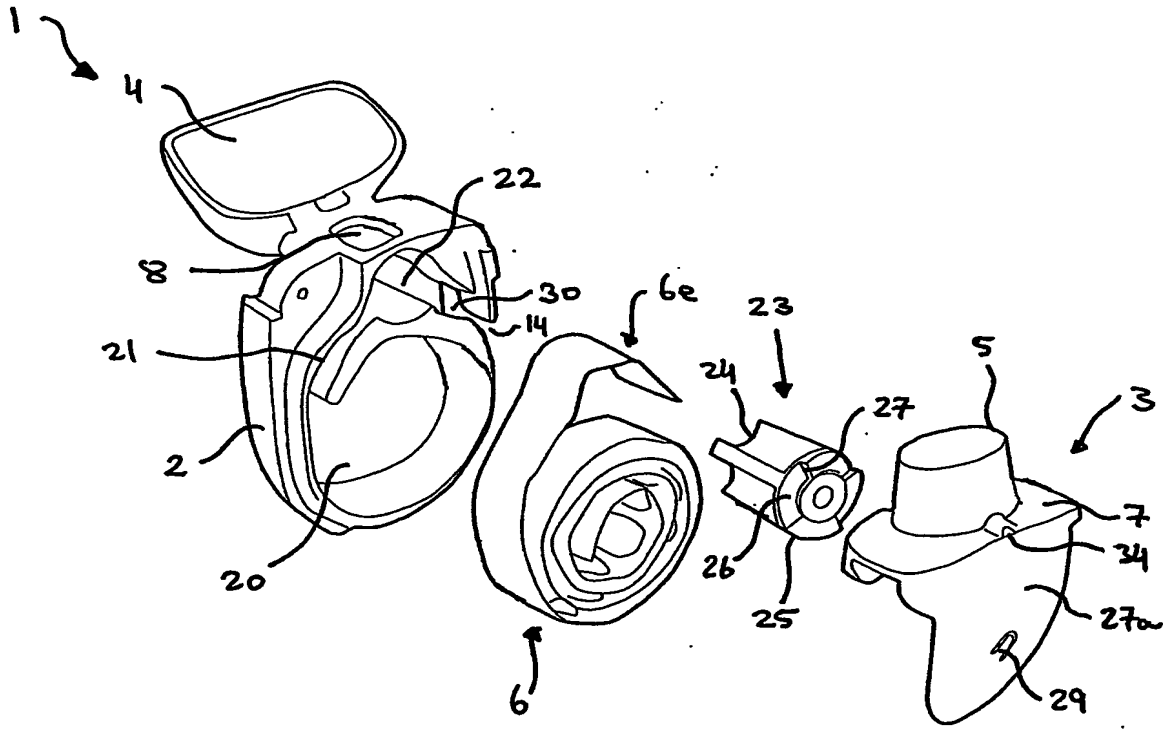


FIGURE 5

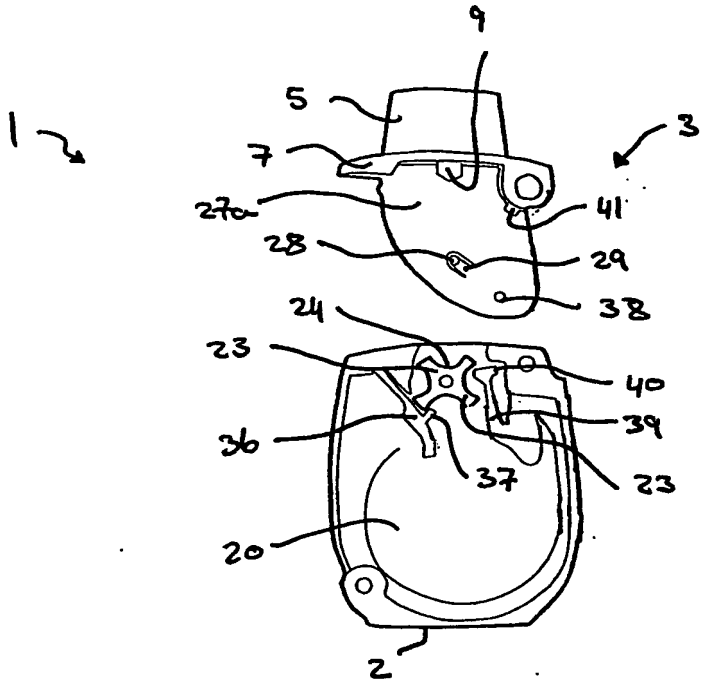


FIGURE 6

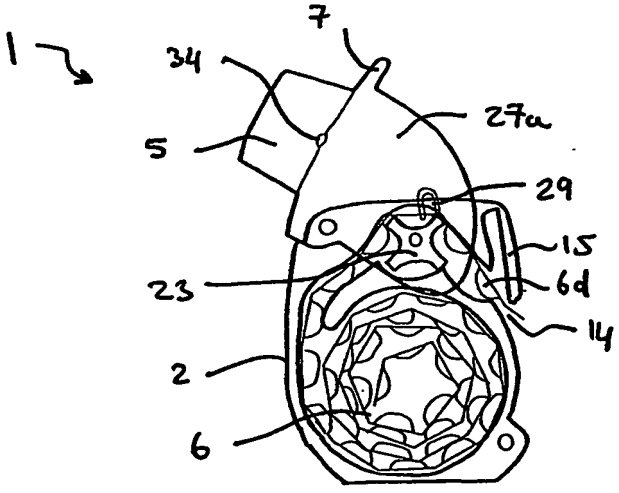


FIGURE 7

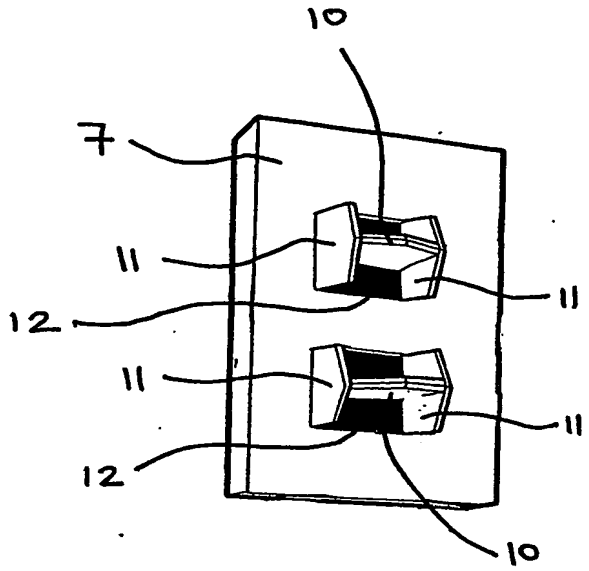


FIGURE 8A

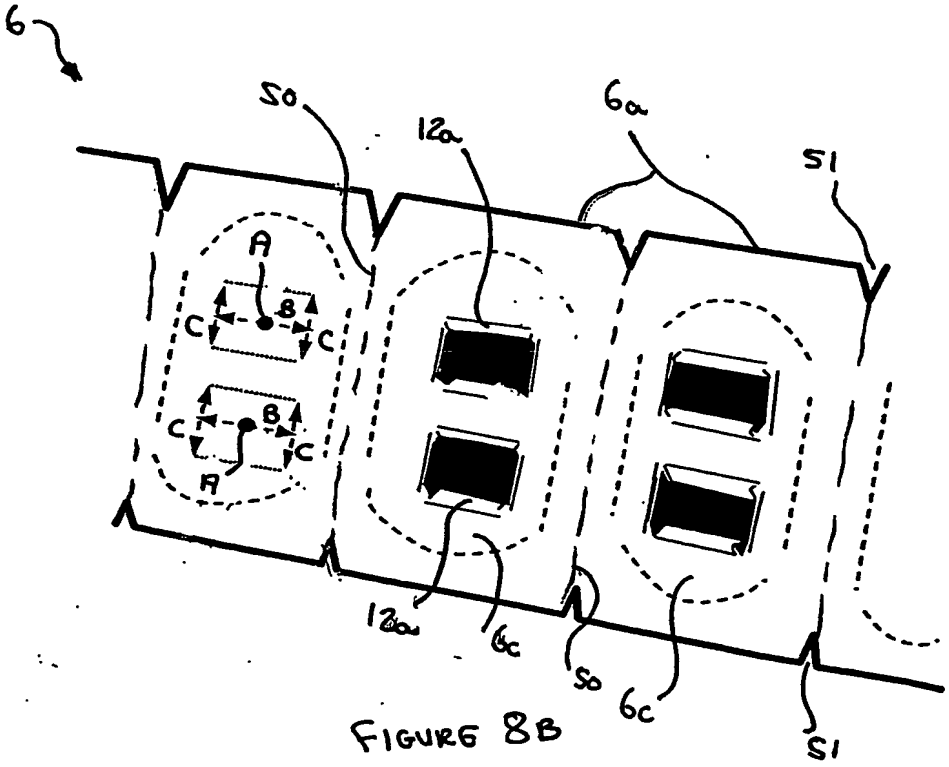


FIGURE 8B

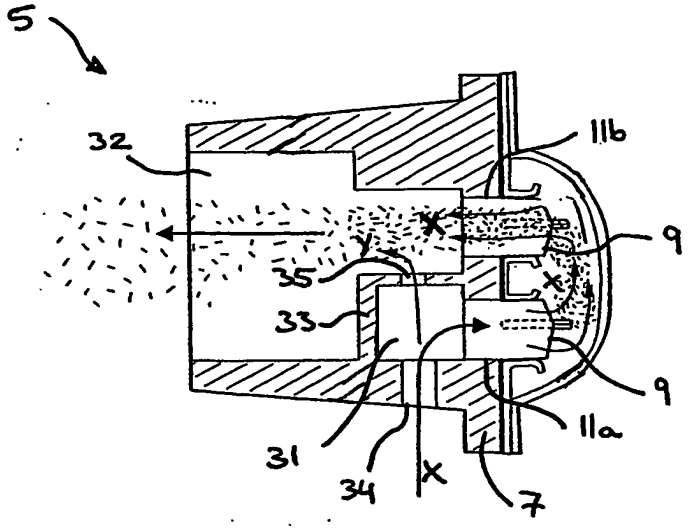


FIGURE 9

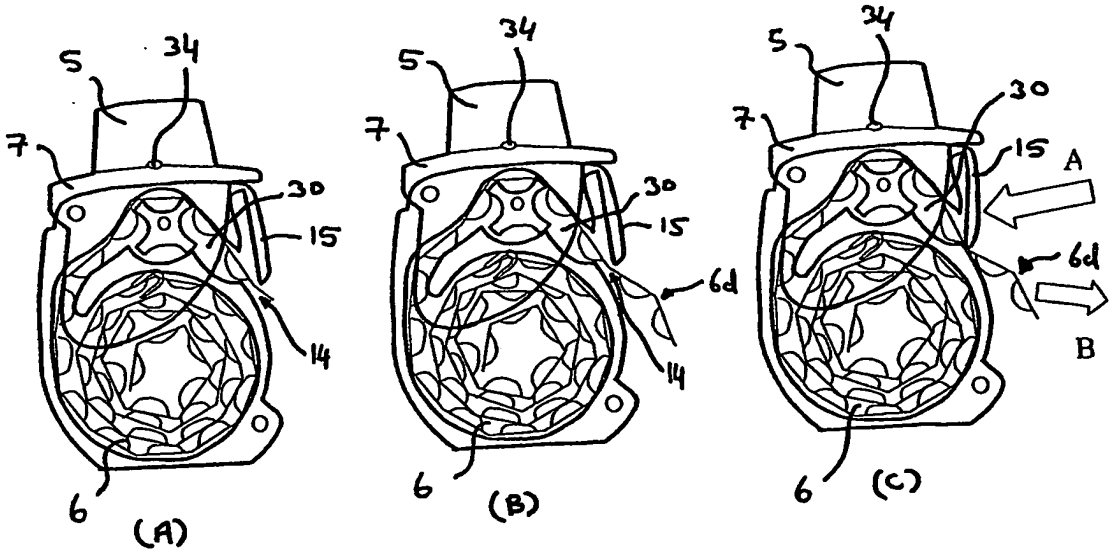


FIGURE 10

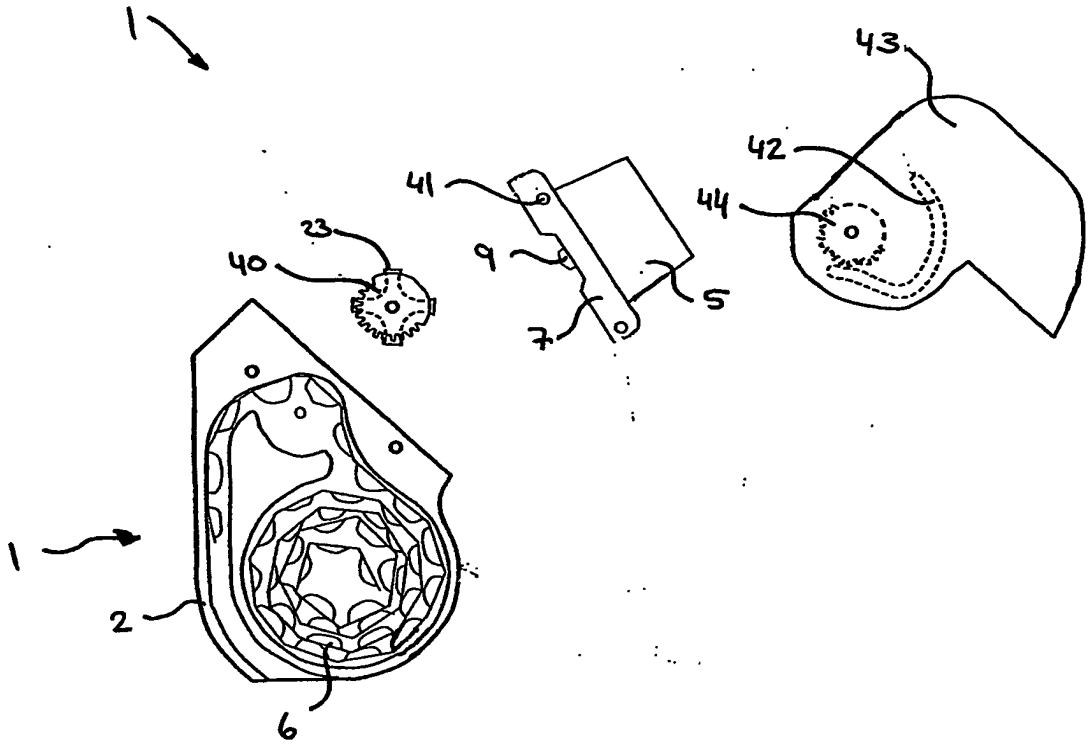


FIGURE 11

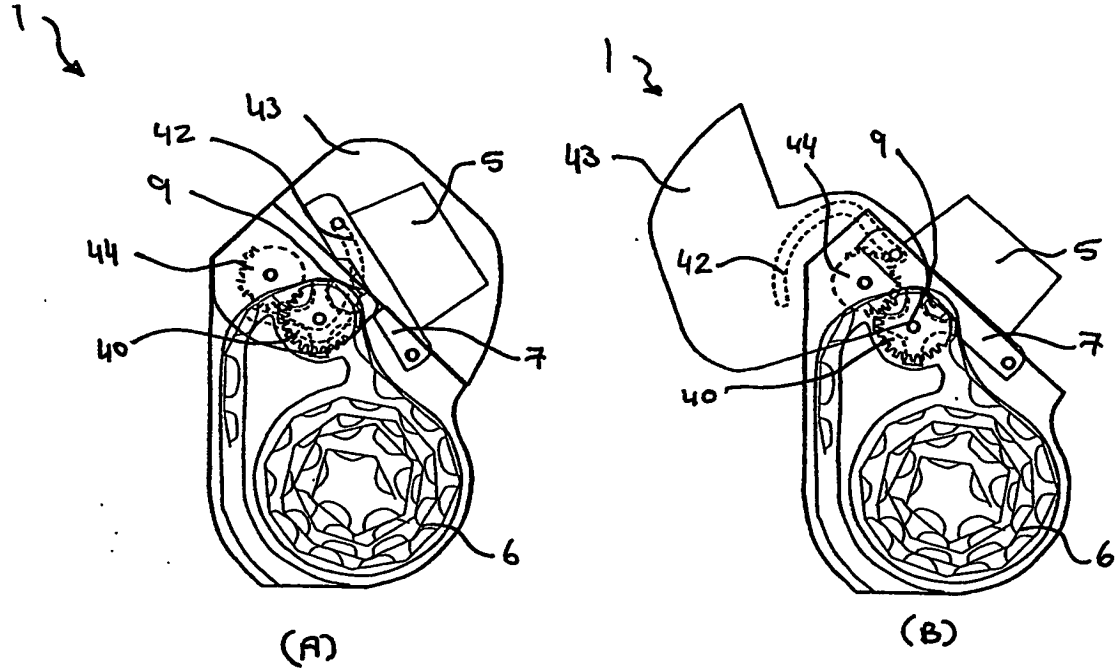


FIGURE 12

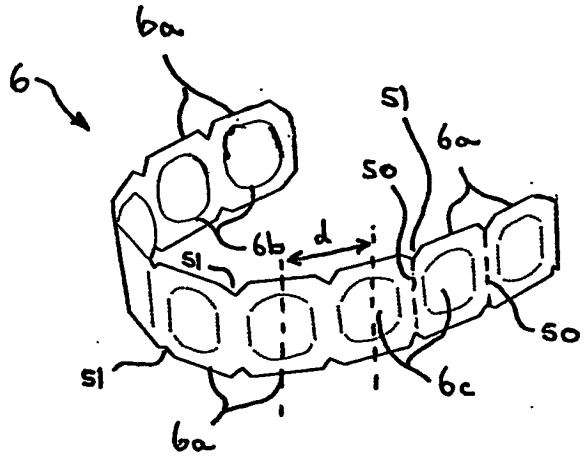


FIGURE 13

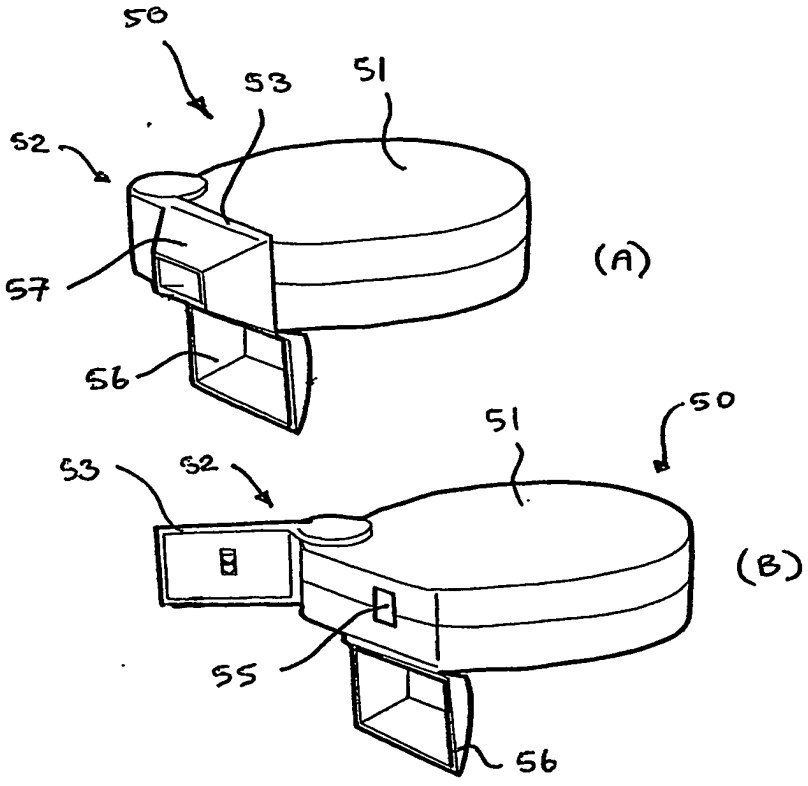


FIGURE 14.

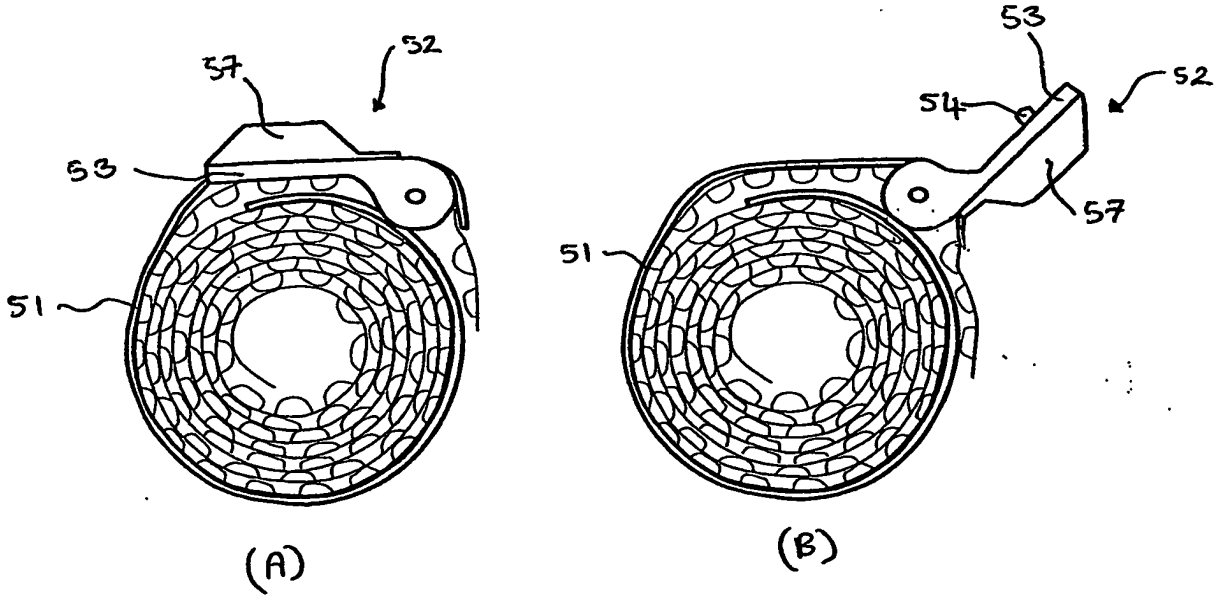


FIGURE 15

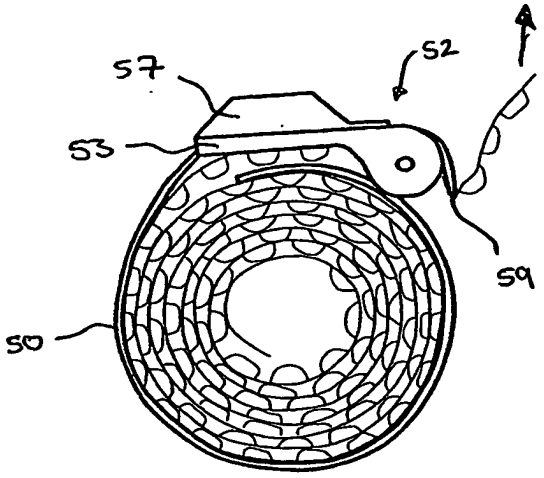


FIGURE 16

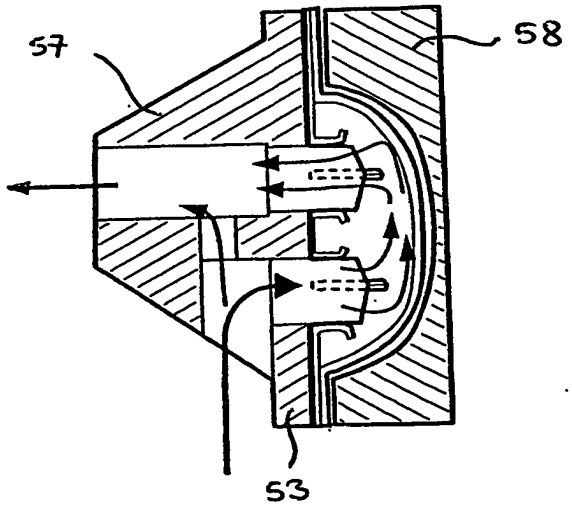


FIGURE 17

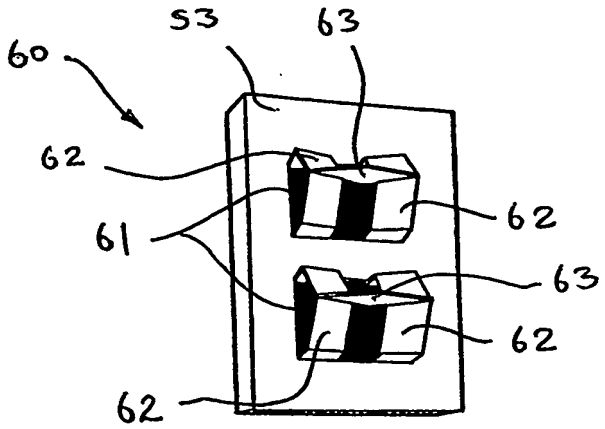


FIGURE 18

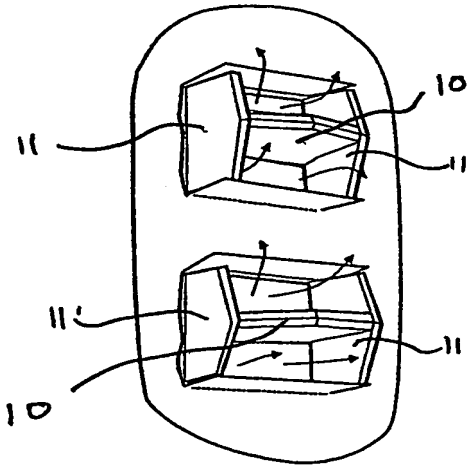


FIGURE 19A

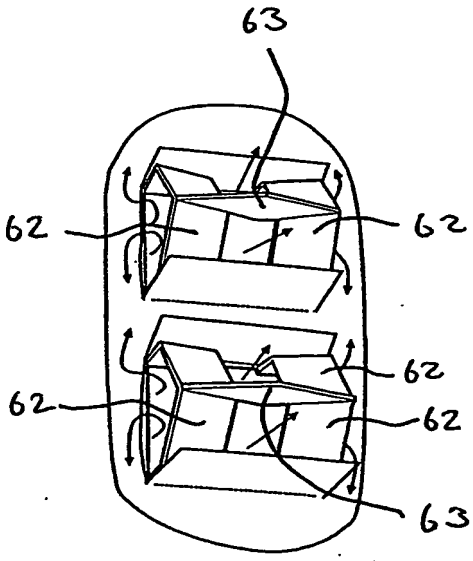


FIGURE 19B

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